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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,767	09/12/2005	William Baxendale	I-2002.016 US	5168

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INTERVET INC.
PATENT DEPARTMENT
PO BOX 318
MILLSBORO, DE 19966-0318

EXAMINER	
HURT; SHARON L	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
08/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,767	BAXENDALE ET AL.	
	Examiner	Art Unit	
	Sharon Hurt	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1 and 8* is/are allowed.

6)☒ Claim(s) *4-7 and 9-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendments to the claims filed June 1, 2007 have been entered. Claims 1 and 7-10 are currently amended.

Status of the Claims

Claims 1 and 4-10 are pending and under examination. Claims 2-3 have been canceled.

Response to Arguments

The rejection of claim 1 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is withdrawn** pursuant Applicant's amendment.

The rejection of claim 1 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the deposited strain of chicken astrovirus type 2 (CAstV-2), does not reasonably provide enablement for an immunologically related chicken astrovirus (CAstV-2) **is withdrawn** pursuant Applicant's amendment.

The rejection of claim 10 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vaccine administered to poultry, does not reasonably provide enablement for a vaccine administered to animals **is moot** in view of the new grounds of rejection.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-7 and 9-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The term "vaccine" implies any preparation intended for active immunological prophylaxis; e.g., preparations of killed microbes of virulent strains or living microbes of attenuated (variant or mutant) strains; or microbial, fungal, plant, protozoal, or metazoan derivatives or products. Although just about any protein when inoculated can cause an immune reaction, the prophylactic nature of this reaction is not guaranteed and has to be experimentally determined. Prophylaxis is defined as the prevention of disease or of a process that can lead to disease. This is achieved by use of an antigenic (immunogenic) agent to actively stimulate the immunological mechanism, or the administration of chemicals or drugs to members of a community to reduce the number of carriers of a disease and to prevent others contracting the disease.

The first paragraph of 35 U.S.C. 112 states: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full,

clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring ingenuity beyond that to be expected of one of ordinary skill in the art (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those In the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention: The claimed invention is drawn to a vaccine for use in protection of poultry against disease caused by avian astrovirus infection. The claims contain the term "vaccine". The office interprets this term as denoting prevention of infection and/or elimination of infection by a virus.

The state of the prior art and the predictability or lack thereof in the art: The art teaches that the efficacy of therapeutics is dependent upon factors such as solubility of the drug, bioavailability at the target site, attainment of effective plasma concentrations, solubility in tissues, biotransformation, toxicity, rate of excretion or clearance, and in the case of antivirals,

propensity for emergence of resistant strains (see Benet et al., pp. 3-32, in The Pharmacological Basis of Therapeutics, 8th ed., 1990, page 3, first paragraph; page 5, second column, last partial paragraph, first two sentences; page 10, the paragraph bridging columns 1 and 2; page 18, the paragraph bridging columns 1 and 2; page 20, last full paragraph; and the paragraph bridging pages 20 and 21. The art further teaches that "the story of drug discovery for viral diseases is replete with failures" (Rice et al., Advances in Pharmacology 33:389-438, 1995; see page 390, first sentence of the third paragraph) and that drugs which are quite effective in the laboratory often reveal disappointing traits in the clinical setting (Rice et al., page 409, last paragraph, second sentence). The art further teaches that while there are antiviral agents which can reduce the incidence of or ameliorate the symptoms of viral infection, there are no treatment methods which can completely prevent viral infection in all cells in every subject and no antiviral agents which can completely eliminate infection in every cell of every subject.

The amount of direction or guidance present and the presence or absence of working examples: The disclosure is limited to examples of: (1) isolation of CAstV-2; (2) immunological characteristics of CAstV-2; and (3) pathogenicity test of CAstV-2 in young chicks. The specification lacks examples, *in vivo* or *in vitro* of a vaccine prepared from CAstV-2 and the efficacy of the vaccine. There are no working examples drawn to absolute prevention of viral infection *in vivo* by employing the claimed method and no working examples showing absolute prevention of infection with viruses *in vivo*. Therefore, there is insufficient evidence to ascertain that the claimed compositions actually completely prevent or totally eliminate viral infection in poultry.

The breadth of the claims and the quantity of experimentation needed: The claimed invention is drawn to a vaccine for protection against avian astrovirus in poultry. Koci et al. teaches there is no experimental evidence that affected poultry develop a protective immune response and that there is little hope for the development of an effective vaccine strategy (page 223). Applicant's specification discloses that CAstV-2 is immunologically distinct from CAstV-1 and other avian astroviruses (page 2, lines 1-3). Because the art teaches a high degree of unpredictability in the ability of antivirals to completely prevent or eliminate viral infection, because the claims encompass absolute prevention and elimination of all virus infections, and because the specification fails to provide an enabling disclosure for absolute prevention or complete elimination, it would require undue experimentation by one of skill in the art to be able to practice the claimed invention commensurate in scope with the claims.

Conclusion

This action is non-final. Claims 1 and 8 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

August 8, 2007

/Bruce Campell/
Supervisory Patent Examiner
Art Unit 1648